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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,174	10/29/2003	Swaminathan Jayaraman	795-A03-004	7393

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3738	

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01/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,174	JAYARAMAN, SWAMINATHAN	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/08 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “caps” must be shown or the feature(s) canceled from the claim(s). Note: cap is understood and interpreted by the Examiner as a *separate* element. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80-95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the ends of the core being covered, does not reasonably provide enablement for "caps". A cap is an object that can be defined to cover something. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. While it is clear that the ends of the core wire are to be covered, the specification does not describe how one would make or use a separate element, such as a "cap". Additionally, the drawings even support that the covering of the ends are integral with the coating about the entire core body, see Figs. 8,12. Thus, because a "cap" is known and defined as a separate element the

disclosure does not enable one to use such objects, or even illustrate such. According to paragraph 116 of Applicant's specification, a coating is applied via dip and spray methods to the core. It is well known that this would provide an integral and uniform coating, not producing a "cap" or separate element. Thus, one of ordinary skill would not be able to make a separate cap.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 80-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "caps" in claim 80 is used by the claim to mean "covering at end of the core wire", while the accepted meaning is "a separate element that can cover." The term is indefinite because the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 80-85,88-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francis et. (6524795) in view of Wolff et al. (WO 91/12779) and Chen et al. (2003/108588). Francis et al. disclose a method of identifying a disease process in a patient, such as restenosis and using angiograms, col. 8, lines 39-41, col. 13, lines 35-57, col. 58, lines 61-67. Francis et al. also disclose to provide a treatment with the patient having the vascular disease and this can include using a drug covered stent, col. 25, lines 5-9. Regarding claim 82, Francis discloses genetic determination for disease susceptibility, col. 9, lines 15-67. With respect to claim 83, Francis discloses detecting vulnerable plaque, col. 13, lines 43-51, col. 16, lines 4-9. However, Francis et al. do not explicitly disclose the stent covered is a plurality of stent preforms with a metallic core encapsulated with caps and a combination of therapeutic agents. Wolff shows (Figs. 1,17) a plurality of stent preforms **12** to form a stent **10**. Fig. 4 shows a stent preform with a metallic core **22** and an outer sheath **14** disposed about the contact surface. Wolff discloses the sheath on the metallic core can include a therapeutic agent that is biostable, page 10, lines 35-37. Wolff et al. also disclose that the sheath is a polymer and can be bioabsorbable, page 12, lines 16-18. It is inherent there is pores in the sheath or coating since it allows for elution of the drug, page 10, lines 36-38. Additionally, Wolff discloses two therapeutic agents could be used, page 15, lines 19,20. It would have been obvious to one of ordinary skill in the art to use the restenosis stent of Wolff et al. with the method of treating a patient by Francis et al. such that it provides a flexible stent and enables the patient to receive multiple treatment materials

to the patient having a restenosis condition. However, Francis as modified by Wolff et al. do not explicitly disclose "caps" on the first and second ends to encapsulate the core. Chen et al. teach a wire **13** form stent, Fig. 2. Chen also teaches that the stent is to be coated entirely such that the ends of the stent wire are encapsulated, paragraphs 45,47,49,66. It would have been obvious to one of ordinary skill in the art to use the teaching of Chen et al. to encapsulate or coat entire wires of a stent such that the ends are capped in the stent of Wolff et al. in the method of Francis such that the vessel wall being treated is not exposed to any rigid structure. Regarding claim 84, Francis et. as modified by Wolff et al. (WO 91/12779) is explained above. Wolff does disclose the therapeutic agents can be cell inhibiting, page 9. However, Francis as modified by Wolff do not explicitly disclose the combination of drugs include rapamycin and cyclosporine. Chen et al. teach that a combination of the drugs rapamycin and cyclosporine A provide a synergistic effect, paragraphs 24,61,68,71,87. It would have been obvious to one of ordinary skill in the art to utilize the combination of drugs of rapamycin and cyclosporine as taught by Chen et al. with the stent of Francis as modified by Wolff et al. such that it enhances the immunosuppression of the smooth muscle cells involved in restenosis. With respect to claim 89, Chen et al. teach that the stent wire material can be a shape memory alloy, paragraph 41. It would have been obvious to one of ordinary skill in the art to substitute metal materials and use a SMA as taught by Chen et al. with the stent of Francis as modified by Wolff et al. such that it is flexible enough for delivery through a tortuous vessel, but stiff enough to not crimp. Regarding claims 92,93, Chen et al. teach a release mechanism over the drug layer or sheath on the core material, paragraph 59.

It would have been obvious to use a release mechanism as taught by Chen et al. with the stent of Wolff et al. used in the method of Francis such that it prevents the drugs from being released too quickly, see Chen.

Claims 86,87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francis et. '795 in view of Wolff et al. (WO 91/12779) and Chen et al. as applied to claim 80 above, and further in view of Bezwada et al. (5468253). Francis et al. in view of Wolff et al. and Chen et al. is explained supra. However, Francis et al. as modified by Wolff et al. and Chen et al. fail to disclose an alternative means of covering the core material of the stent. Bezwada et al. teach a stent can have tape including a drug, col. 6, lines 19-21,27. It would have been obvious to one of ordinary skill in the art to use alternatively, tape with a drug on the stent as taught by Bezwada et al. with the stent of Francis modified with the stent filaments of Wolff et al. modified by Chen et al. such that it can be applied with the amount necessary as determined by the doctor.

Claims 94,95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francis et. '795 in view of Wolff et al. (WO 91/12779) and Chen et al. as applied to claim 80 above, and further in view of Barclay et al. (2002/77693). Francis et al. in view of Wolff et al. and Chen et al. is explained supra. Wolff et al. does disclose multiple polymer layers can be used, Fig. 3B and page 15, lines 11-21. However, Francis et al. as modified by Wolff et al. and Chen et al. fail to disclose the drug is coated over the sheath. Barclay et al. teach (Fig. 5E) a stent **139** can have an outer sheath **141A** and then a drug layer **147** and then a release layer **143**. This enables the drug to be delivered to the lumen tissue and not the blood. It would have been obvious to place

the drug layer on a sheath layer and then a release layer of polymer on the stent as taught by Barclay et al. with the stent of Francis modified with the stent filaments of Wolff et al. modified by Chen et al. such that it can treat the lumen.

Response to Arguments

Applicant's arguments with respect to new claims 80-95 have been considered but are moot in view of the new ground(s) of rejection. Regarding the Applicant's arguments filed 11/10/08 about the Francis reference, they have been fully considered but they are not persuasive. Applicant alleges the reference does not teach agents for use in treating diagnosed disease pathology. This is clearly taught in the reference and imaging techniques are mentioned as referred to in the action above. The stent and therapeutic material disclosed in the Francis reference is clearly used for diagnosed disease processed determined by the doctor or cardiac surgeon who are highly skilled in the area of cardio pathology and diagnosing potential risks. With respect to the Wolff reference, Applicant argues there are no caps on the core wires. While it may not be explicitly disclosed, it is well known in the coating art that when applying coatings to a substrate that the entire object being coated would be covered and thus results in "capping" the ends. Thus, the action above addresses this concern by Applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738